

## PUBLIC NOTICE AND AGENDA

DHS IRB Meeting, March 9, 2005, Room 210, 9 a.m.

### PROTOCOLS FOR REVIEW

- **Brad W. Lundahl, PhD**, University of Utah College of Social Work, Parent Education: Testing a relationship enhancement program, DHS affiliated agency is the Division of Child and Family Services (DCFS), DHS IRB # 050278. **New Research (Under Conditional Approval) and Change Request. RISK LEVEL:** ☐ < Minimal risk; ☒ Minimal Risk; ☐ > Minimal risk but with direct benefit to subjects; ☐ > Minimal risk but no direct benefit to subjects.
- **Shirley Dobbin, Ph.D.**, National Council of Juvenile and Family Court Judges, Evaluating Front-Loading Strategies in Child Abuse and Neglect Cases: Are We Improving Outcomes for Children and Families, **New Research**, DHS affiliated agency is the Division of Child and Family Services (DCFS), DHS IRB # 050282. **RISK LEVEL:** ☐ < Minimal risk; ☐ Minimal Risk; ☐ > Minimal risk but with direct benefit to subjects; ☐ > Minimal risk but no direct benefit to subjects.
- **Ruth McRoy, Ph.D.**, University of Texas at Austin, AdoptUSKids Research Project – The Collaboration to AdoptUSKids, **New Research**, DHS affiliated agency is the Division of Child and Family Services (DCFS), DHS IRB # 050281. **RISK LEVEL:** ☐ < Minimal risk; ☐ Minimal Risk; ☐ > Minimal risk but with direct benefit to subjects; ☐ > Minimal risk but no direct benefit to subjects.
- **William McMahon, M.D.**, University of Utah, Genetics of Autism, DHS IRB # 030223, **Annual Review and Change Request**, DHS affiliated agency is DSAMH. **RISK LEVEL:** ☐ < Minimal risk; ☒ Minimal Risk; ☐ > Minimal risk but with direct benefit to subjects; ☐ > Minimal risk but no direct benefit to subjects.

### PROTOCOL DEVIATIONS

- **Michael Stevens, MD**, Valley Mental Health (VMH). Notification of a protocol deviation was received from VMH on February 17, 2005, that is applicable to the CAFÉ Study, DHS IRB # 020183. It involves Participant # 00210009 NAM.

The protocol deviation is that the participant was on the study medication for 54 weeks, rather than the consent specified 52 weeks. The extra amount of time on study medication was due to the extraordinary (positive) response that this subject had with the study medication; therefore, requiring extra time to coordinate and receive the unblinding study medication information and transfer his treatment to regular clinical care. Due to the extra time allowed by the study for this patient to remain on the study medication the patient was able to successfully transition. Mary FAXed the letter to Dr. Spencer on 02-23-05. Dr. Spencer reviewed it and had no concerns with continuing this patient on the study medication for 2 extra weeks until the unblinding could be completed, since he had such a good response to the treatment.

- **Connie Kitchens**, DSAMH, Utah Higher Education Health Behavior Survey, affiliated DHS agency is the Division of Substance Abuse and Mental Health (DSAMH), DHS IRB # 030213.

On February 22, 2005, Connie Kitchens sent Mary Caputo an e-mail indicting that Salt Lake Community College sent out an e-mail to approximately 20,000 students to invite them to participate in the Utah Higher Education Health Behavior Survey. This was not addressed as a method in our IRB application, nor did the campus check with Connie to see if it would be okay to use this protocol. The method that had been approved is to send e-mails to a randomized group of students. SLCC told Connie that there is no way to randomize their list.

Connie also indicated they originally were using another method from the protocol - they had classes randomly selected and were going into the classrooms and making announcements for the students to go on line and participate. They handed out an "invitation" to the students with the web address for them to go to. When they saw this method wasn't working very well they chose to try another method.

Connie stated that "On the bright side - they have had a large response of over 1,000 students but this is now not a truly random sample". Connie asked what was to be done since the IRB protocol wasn't followed.

Mary thanked Connie for letting us know of the protocol deviation and told her that letting the IRB know of the deviation was the appropriate thing to do. This was certainly not anything Connie did and does not appear to change the risk level. Mary asked Connie to please get us a copy of the e-mail that went to students so that we can be assured that the survey was voluntary and that participants were not subject to any coercion.